

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

UNITED STATES,

Plaintiffs,

V.

ENVIGO RMS, LLC,

Defendant.

Case No. 6:22-cv-28-NKM

**ENVIGO’S RESPONSE IN OPPOSITION TO THE UNITED STATES’ MOTION FOR
PRELIMINARY INJUNCTION**

Notwithstanding the voluminous filings by the United States early on Saturday morning, there is actually very little that should remain in dispute in this case. Since the Court entered its temporary restraining order on May 21, Envigo RMS, LLC (“Envigo”) has repeatedly expressed to counsel for the United States its willingness to close its Cumberland, Virginia facility once it is permitted to do so. Envigo and its parent company, Inotiv, Inc. (“Inotiv”) believe that doing so would eliminate all the concerns raised in the United States’ Complaint and other filings. However, under the Court’s May 21 Order and the relief requested by the United States’ Motion for Preliminary Injunction (“Motion”), Envigo is prohibited from taking prudent measures to remove dogs from the facility, including as necessary to fulfill existing research orders.

Any order entered on the United States' Motion should allow for the orderly wind-down of the facility. Specifically, Envigo does not object to the United States' requests 1-10 and 13-14. Instead, Envigo takes issue only with requests 11 and 12. These directives would prevent the orderly wind-down of the Cumberland Facility because they would bar the transfer of a

subset of dogs to facilities and research institutions contractually entitled to receive them—impacting drug development and testing.

Envigo and Inotiv take the issues raised in this case very seriously. Since this case was filed the companies have worked tirelessly to upgrade and improve the facility and its programs. Over the last year, Envigo and Inotiv have invested millions of dollars towards bringing the facility into compliance with the Animal Welfare Act (“AWA”) and related regulations. In recent weeks, the facility and its personnel have been singularly focused on complying with the Court’s Order. These efforts are ongoing and Envigo and Inotiv are committed to ensuring the facility becomes and remains fully compliant with all animal welfare and other regulations for as long as it is in operation.

In light of the recurring nature of some of the challenges of operating the Cumberland facility, Envigo and Inotiv have determined it is in the best interest of the companies and all stakeholders to wind-down the facility. This would involve transferring the dogs currently housed at the facility to new owners and then closing the facility. Closing down the facility in this manner would serve the dual purposes of removing beagles from the Cumberland facility and advancing pharmaceutical research. Accordingly, Envigo does not oppose many aspects of the relief sought in the motion for preliminary injunction. Envigo opposes the United States’ Motion only to the extent the relief requested would prevent Envigo from safely relocating the approximately 3,000 dogs currently housed at the facility, and to winding down its operations.

FACTUAL BACKGROUND

Envigo is the second largest producer of canines for use in medical research, producing approximately 25 percent of all beagle dogs used in medical research and drug development in the United States. Declaration of John Sagartz, DVM, PhD, DACVPM, dated June 13, 2022 (“Sagatz Decl.”) ¶¶ 5, 8. The Cumberland facility is a USDA-regulated animal production

facility focused on the generation of purpose-bred beagle dogs. *Id.* ¶ 6. These purpose-bred beagle dogs are essential for biomedical research and the development of lifesaving drugs, including medicines designed to treat cancer and autoimmune disorders. *Id.*

In November 2021, Envigo was acquired by Inotiv, a contract research organization specializing in nonclinical and analytical drug discovery and development services. *Id.* ¶ 5. Since the acquisition, Inotiv and Envigo have been working diligently to address the concerns raised about the Cumberland facility. *Id.* ¶¶ 9-11.

In the months leading up to the May 18, 2022 search warrant, Envigo, and later Inotiv, worked diligently to improve conditions at the facility. Sagartz Decl. ¶ 10. These improvements include installing over 1,200 new aluminum doors; correcting gaps in enclosures; relocation of and upgrading the flooring in the weaning and whelping area; purchasing over 500 whelping boxes; installing generators and cooling towers to regulate temperature; hiring a board-certified veterinarian behaviorist to assist with the aggression issues; transferring veterinary staff from other Inotiv facilities; increasing salaries and offering other incentives to bolster its workforce; and hiring a contract veterinarian to assist with dentals; as well as hiring additional staff. Declaration of Carmen Wilbourn, dated June 13, 2022 (“Wilbourn Decl.”) ¶ 4; Sagartz Decl. ¶ 10.

Since this Court’s May 21, 2022 Order, Envigo and Inotiv have continued to devote significant resources to compliance and to implementing other improvements at the facility. Envigo has assembled a team of licensed veterinarians to assess the conditions at the facility and to provide continuous care to the beagles housed at the facility. Declaration Len Edward Murray, DACLAM, DACVPM (“Murray Decl.”) ¶ 4. In addition, Envigo employs a team of animal care technicians who care for the animals. *See id.*

Envigo’s attending veterinarian has implemented a dietary plan that ensures that every beagle is provided uncontaminated, wholesome, palatable food of sufficient quantity and nutritive value and that is appropriate for the individual animal’s age and condition. *Id.* ¶ 7. In addition, the facility has redundant systems in place to ensure that all dogs have access to potable water. *Id.* ¶ 8. Envigo’s staff has also purchased 2,000 steel food/water bowls for gradual introduction into the enclosures, added black rubber mats to each enclosure to address concerns with flooring, installed partitions for enclosures, installed air conditioning units in all necessary areas of the facility, including the dog housing areas, and sourced large volumes of compounded medications to treat all 3,188 dogs in the facility for *Giardia* upon identifying a single positive case. Wilbourn Decl. ¶¶ 6; 11. In the rare instances when fighting has occurred, the staff has immediately separated and treated dogs. *See* Murray Decl. ¶ 9.

In addition, Envigo’s veterinary care team also administered all medically appropriate treatment recommended by the United States’ veterinarians within 10 days of the Order. Murray Decl. ¶¶ 10-11. The team has also undertaken several preventative care efforts, including testing for various parasites. *Id.* ¶¶ 12; 14. In compliance with the Court’s May 21 Order, Envigo immediately ceased—and has not resumed—breeding, selling, or otherwise dealing in beagles at the Cumberland facility. Wilbourn Decl. ¶ 7. Envigo has not euthanized any dogs at the Cumberland facility without the consent of counsel for the United States since the issuance of the Court’s Order. Declaration of Jeannie Perron, JD, DVM, dated June 12, 2022 (“Perron Decl.”) ¶ 9. Pursuant to the Order’s notice requirements, Envigo has also provided approximately 5,000 pages of medical records, birth notices, and necropsy reports to counsel for the United States. *Id.* ¶ 5; *see id.* ¶¶ 6-8.

ARGUMENT

Envigo has complied and continues to comply—to the fullest extent possible—with the requirements in this Court’s May 21 Order and has no objection to the vast majority of the relief requested by the United States’ Motion. This includes continuing to comply with the requirements for handling, housing, feeding, watering, sanitation, and adequate veterinary care. Mot. at 2-3 (requests for relief 1-10 and 13-14).

Envigo only opposes the United States’ Motion to the extent it seeks to prevent Envigo from taking prudent measures to remove dogs from the facility. *See* Mot. at 3 (requests for relief 11-12). Under the United States’ proposed preliminary injunction, Envigo would be barred from transferring dogs from the Cumberland facility for an indeterminate period of time until the facility is deemed “in full compliance with the terms of [the Order granting injunctive relief] and the Court’s May 21, 2022 Order.” Mot. at 3, ¶ 12. Said differently, if granted in full, the Motion would prevent Envigo from, for example, winding down the Cumberland facility and safely transferring dogs to new homes without first bringing the facility into full compliance with the AWA. *See id.* ¶¶ 11-12.

However, in light of the serious allegations raised in the United States’ Complaint and recurring challenges of operating the Cumberland facility, Inotiv and Envigo are willing to wind down the facility’s operations. To do so would require transferring all dogs currently housed there to new homes, both through adoption and through fulfillment of Envigo’s existing contractual obligations to its customers. Permitting Envigo to remove dogs from the facility by fulfilling existing contractual commitments, for example, would allow Envigo to transfer more than 500 dogs to new homes within the next 30 days. Sagartz Decl. ¶ 17. Further, allowing Envigo to fulfill existing orders for dogs, as part of this transfer and wind-down process, would also minimize the immediate and long-lasting impact on ongoing and important pharmaceutical

research of indefinitely halting operations at the Cumberland facility until the Parties can reach a resolution regarding Envigo's compliance with the AWA. *See id.* ¶¶ 15-17.

CONCLUSION

For the reasons stated above, Envigo respectfully requests that this Court permit Envigo to take prudent measures to remove dogs from the facility and to allow for the orderly wind down of the facility.

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Respectfully submitted,

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